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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,442	02/18/2004	Chengde Wu	TEX4542P0491US	3434
20583	7590	12/13/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			GRAZIER, NYEEMAH	
			ART UNIT	PAPER NUMBER

1626

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/781,442	Applicant(s) WU ET AL.	
	Examiner Nyeemah Grazier	Art Unit 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-15 is/are pending in the application.
- 4a) Of the above claim(s) 7, 12, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6, 8-11 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/10/06</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **I. ACTION SUMMARY**

Claims 6, 8-11, and 13 are currently pending. Claims 12, 14, and 15 are withdrawn from further consideration by the Examiner because Claims 7, 12, 14, and 15 are drawn to a non-elected invention. 37 C.F.R. § 1.142(b).

### **II. RESPONSE TO AMENDMENTS/ARGUMENTS**

#### **A. REJECTION UNDER 102(b)/OUTSTANDING REJECTIONS**

J. Med. Chem. 1999, 42, pp. 4485-4499: Applicants remarks filed on October 10, 2006 have been fully considered and is persuasive because the reference teaches an isomer of the instant invention. Thus, the rejection is withdrawn.

WO 98/13366: Applicants remarks filed on October 10, 2006 have been fully considered and is NOT persuasive for the same reasons stated in the Action dated July 10, 2006. The rejection is maintained because the invention is anticipated. *See, e.g.*, WO 98/13366, p. 63, l. 32-33, Compound "N-3,4-dimethyl-5-isoxazolyl)-3-(phenylaminocarbonyl)thiophene-2-sulfonamide.

WO 02/28353: Applicants remarks filed on October 10, 2006 have been fully considered and is persuasive in light of the amendments to the claims wherein the phenyl is not substituted with halogen. The rejection has been obviated.

#### **B. OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION**

Applicant's remarks filed on October 10, 2006 regarding the outstanding ODP rejection has been fully considered. The Applicant requested to hold the rejection in abeyance until the claims are in condition for allowance. The rejection is therefore maintained.

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### III. REJECTION(S)

As previously mention in the Action dated July 10, 2006, "aryl" is defined in the instant Specification as a carbocyclic or heterocyclic ring. See, Action dated July 10, 2006, p. 3, 2<sup>nd</sup> paragraph.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

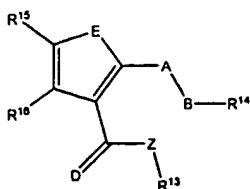
*Graham v. John Deere Co.* set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. § 103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966).

Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 8-11, and 13 are rejected under 35 U.S.C. § 103(a) as being obvious independently over (1) *Wu, et al.*, **J. Med. Chem.**, 1999, vol. 42, pp. 4485-4499; (2) *Wu et al.*, WO 98/13366; and (3) *Weinstock et al.*, WO 02/28353.

The instant invention is drawn to products of Formula (II)



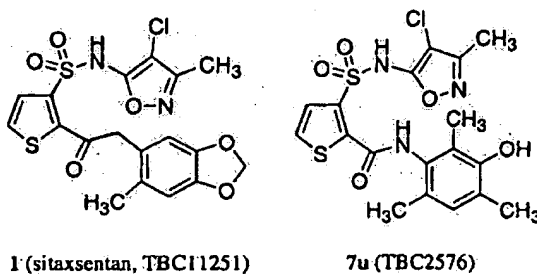
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Wherein D is oxygen or sulfur; A is NR17 or SO2; and wherein A is NR17, B is SO2 and vice versa; R13 and R14 are each "aryl" ("aryl" has been defined in the Specification as including carbocyclic or heterocyclic rings).

**The Scope and Content of the Prior Art (MPEP §2141.01)**

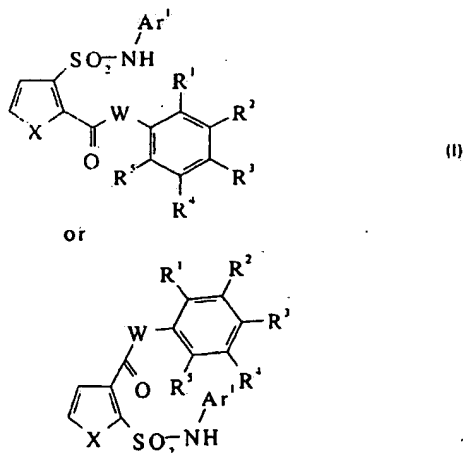
(1) Wu et al., J. Med. Chem., 1999, vol. 42, pp. 4485-4499:

Wu et al. teaches endothelin antagonists. Namely non-peptide ETA-selective antagonists, compound TBC 11251 and 7u, See, e.g., p. 1, chart 1.



(2) Wu et al., WO 98/13366:

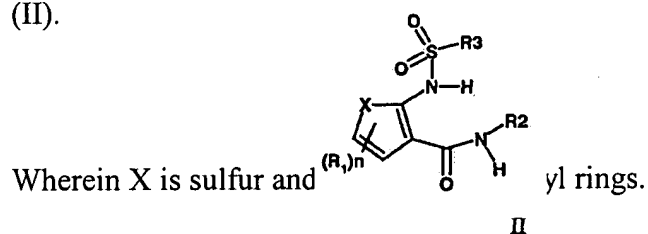
The publication teaches sulfonamides and derivatives thereof that modulate the activity of endothelin, namely N-(isoxazoly)thienylsulfonamides. The invention is drawn to the formula(I) which include positional isomer thereof.



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(3) WO 02/28353 A2:

The publication teaches thiophene compounds useful for treatment of chronic renal failure and uremic bone disease. The compound of the invention, relative to the rejection, is drawn to the compounds and compositions and methods of making and using formula (II).

**The Difference Between the Prior Art and the Claims (MPEP §2141.02)**

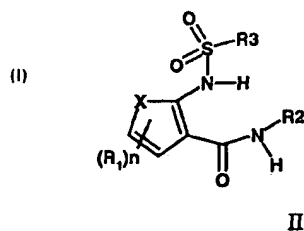
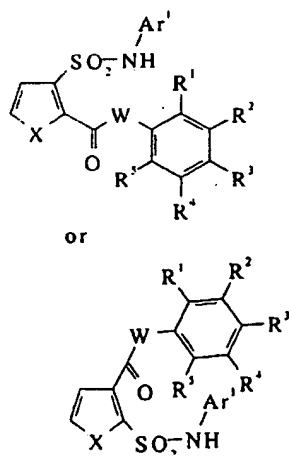
The difference between the instant invention and the prior art of record varies.

(1) Wu et al., J. Med. Chem., 1999, vol. 42, pp. 4485-4499:

The difference between the instant invention and prior art (1) is in scope and form. The prior art is drawn to a positional isomer of the instant invention. The instant invention is drawn to 2-sulfamoyl-3-thiophenecarboxamides, while the *Wu et al.* reference is drawn to 3-isoxazolylsulfamoyl-2-thiophenecarboxamides. Additionally, the instant invention is broader in scope than the art of record.

(2) and (3) Wu et al., WO 98/13366 and WO 02/28353 A2:

The difference between the instant invention and the prior art of reference (2) is in scope. The preferred embodiment of the art of record is drawn to formula (I) and formula (II) respectively:



The invention of the art of record is drawn specifically to 2-sulfonamide-3-carbamylthiophenes. While in the instant invention when A is SO<sub>2</sub>, B is NR<sup>17</sup> and vice versa.

**Resolving Level of Ordinary Skill in the Pertinent Art**

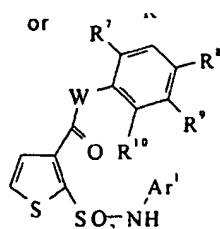
The pertinent art is generally medicinal chemistry. One of ordinary skill in the pertinent art of medicinal chemistry, would have the motivation to make and use to instant invention because there is motivation to make in the instant compounds in the abovementioned references which teach compounds useful pharmaceutical agents.

**Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)**

The motivation to make claimed compound derives from the expectation that structurally similar compounds are generally expected to have similar properties and have similar utilities. In re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979).

It is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to a person of ordinary skill in the art. In re Boe, 148 USPQ 507 (CCPA 1966). For an invention to be obvious, two things must be found in the prior art: 1) the suggestion of the invention, and 2) the expectation of success. In re Vaeck, 20 USPQ.2d 1438, 1441 (Fed. Cir. 1991).

The prima facie case for obviousness is derived from the preferred teaching of the references. For instance, the preferred embodiment of the WO 98/13366 publication is the compounds of formula (III). See, p. 25, for example.



Wherein "w" is preferably NH, see p. 29; and Ar1 is preferably 4-chloro-3-methyl-5-isoxazolyl.

The expectation of success is derived from the prior art of reference because the publication discloses species drawn to the abovementioned core. Additionally, the specification of the publications teaches how to make the compounds and disclose protocol used to test the compounds for its inhibitory effects. Thus, although the claims are not identical, the prior art of reference suggests the instant invention.

#### **IV. OBJECTION(S)**

Claim 11 is objected to for the following minor informalities:

Claim 11 should be amended by inserting ---the group consisting of --- after the phrase "selected from."

#### **V. CONCLUSION**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Thursday and every other Friday from 8:30 a.m. - 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Very truly yours,



**Nyeemah Grazier, Esq.**

*Patent Examiner, Art Unit 1626*

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